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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,693	11/28/2000	Gyula Hadlaczky	24601-402D	7857

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/25/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/724,693	HADLACZKY ET AL.	
	Examin r	Art Unit	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____ .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11-19 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) 6, 18, 19, 32 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11-17, 30, 31, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9, 12, 15, 18, 23, 24</u> | 6) <input type="checkbox"/> Other: ____ . |

Art Unit: 1632

DETAILED ACTION

1. Applicant's election with traverse of the invention of claims 1-5, 11-17, 30 and 34, directed to a method of amplifying a nucleic acid molecule in an animal cell by targeting it to an amplifiable region of a chromosome in Paper No. 21 is acknowledged. The traversal is on the ground(s) that there has been no demonstration that the groups are distinct and that the examiner has not cited any art that amplification events in plant and animals require different reagents. This is not found persuasive because as noted in the previous office action, the methods carried out in a cell in an animal cell and a plant are classified in different subclasses. Additionally, it is art recognized that plant and animal cells have different structure and therefore the steps of a method carried out in an animal cells cannot be used for practicing the method in an animal cell. Applicants' arguments regarding esoteric technology and citation of MPEP are misplaced since the cited section of MPEP deals with art rejection and in the instant case, there is no art rejection, rather restriction. It is noted that the cited MPEP 2144.03 deals with art rejection not with restriction. Applicants are referred to MPEP 803 for restriction practice, which states:

"CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 06.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and
- (B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, §806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

GUIDELINES

Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases."

In the instant case, examiner has met this guideline and therefore the requirement is still deemed proper and is therefore made FINAL.

2. It is noted that claims 31, 33 and 34 were inadvertently not put in any of the restriction groups and should have been included in group I. Accordingly, group I, containing claims 1-5, 11-17, 30, 31, 33 and 34 directed to a method of amplifying

Art Unit: 1632

a nucleic acid molecule in an animal cell by targeting it to an amplifiable region of a chromosome are under consideration.

3. Claims 6, 18, 19, 32 and 35 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 21.

4. Claims 20-29 have been cancelled.

5. The name of Aladar A. Szalay as a joint inventor has been deleted.

Priority

6. Page 1 of the specification lists a long list of US applications to which the instant application claims priority and relationship and most of these are CIP relationships. In the absence of any description as to what was added to all these claimed parent application and when was the claimed invention of the instant application was first described, for the claimed invention of the instant application is assigned the filing date of April 10, 1997, the filing date of the US nonprovisional application 08/835,682, of which the instant application is a continuation.

Information Disclosure Statement

7. Ref# S and T in the IDS filed 6-3-03 have not been considered because they do not provide the complete citation. A publication without volume number and year of publication cannot be published in a patent.

8. A line has been drawn through the ref#B in the IDS filed 10-10-02 because it is a duplicate of the reference A.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1632

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 11-17, 30, 31, 33 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 30 and 33 are incomplete and indefinite because they do not recite a positive step.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5, 11-17, 30, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Wegner et al (DNA and Cell Biology 9:311-0321, 1990).

Wegner et al teaches an amplification promoting sequence from mouse genomic DNA that has been isolated from mouse rDNA nontranscribed spacer region. The art teaches plasmid vectors that have the DNA fragment, methods of transfecting the plasmids in a mammalian Ltk- cells, identification of cells that have amplified plasmid and that the plasmid is integrated into the genome of the cell (see the entire document).

Therefore, the claimed invention is anticipated by Wegner et al.

13. Claims 1-5, 11-17, 30, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Stolzenburg et al (Chromosoma 103:209-214, 1994).

Stolzenburg et al teaches three domains of the origin of replication of mammalian chromosome, the DHFR locus in CHO cells and compares them to amplification promoting sequences from mouse genomic DNA that has been isolated

from mouse rDNA nontranscribed spacer region. The art teaches plasmid vectors that have the DNA fragments comprising the amplification promoting sequence and DHFR locus, methods of transfecting the plasmids in a mammalian Ltk- cells, identification of cells that have amplified plasmid and that the plasmid is integrated into the genome of the cell (see the entire document).

Therefore, the claimed invention is anticipated by Stolzenburg et al.

14. Claims 1-5, 11-17, 30, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Hemann et al (DNA and Cell Biology 13:437-445, 1994). Hemann et al teaches high copy expression vectors comprising amplification promoting sequences. The art teaches plasmid vectors that have the DNA fragments comprising the amplification promoting sequence, methods of transfecting the plasmids in a mammalian Ltk- cells, identification of cells that have amplified plasmid and that the plasmid is integrated into the genome of the cell (see the entire document).

Therefore, the claimed invention is anticipated by Hemann et al.

15. Claims 1-5, 11-17, 30, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Wegner et al (Nucleic Acid Research 17:9909-9931, 1989).

Wegner et al teaches an amplification promoting sequence from mouse genomic DNA that has been isolated from mouse rDNA nontranscribed spacer region. The art teaches plasmid vectors that have the DNA fragment, methods of transfecting the plasmids in a mammalian Ltk- cells, identification of cells that have amplified plasmid and that the plasmid is integrated into the genome of the cell (see the entire document).

Therefore, the claimed invention is anticipated by Wegner et al.

16. Claims 1-5, 11-17, 30, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al (Gene 129:263-268, 1993).

Meyer et al teaches inhibition of HIV-1 replication by a high copy expression vector expressing antisense RNA for reverse transcriptase. The vector comprises the amplification promoting sequence of murine rDNA. The art teaches plasmid


Art Unit: 1632

vectors that have the DNA fragments comprising the amplification promoting sequence and methods of transfecting the vector in a Jurkat cells and identification of cells that have amplified plasmid (see the entire document).

Therefore, the claimed invention is anticipated by Meyer et al.

17. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



**RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER**

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632